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Sent: Fri 7/10/2020 2:31:20 PM (UTC)
To: Charles Boyd <CharlesB@Safechain.com>, "Adam Brosius (Contact)" <adam@pharmasales.com>
Subject: DSCSA information

Good morning-

In order for us to continue to purchase HIV medication from Boulevard 9229, we will need them to comply with the Drug Supply Chain Security Act. They are required to provide us information about where the drugs came from as is clearly stated in section 25 of the act:

`(c) Wholesale Distributor Requirements.--

``(1) Product tracing.--

``(A) In general.--Beginning not later than January 1, 2015, the following requirements shall apply to wholesale distributors:

``(i) A wholesale distributor shall not accept ownership of a product unless the previous owner prior to, or at the time of, the transaction provides the transaction history, transaction information, and a transaction statement for the product, as applicable under this subparagraph.

``(ii)(I)(aa) If the wholesale distributor purchased a product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer, then prior to, or at the time of, each transaction in which the wholesale distributor transfers ownership of a product, the wholesale distributor shall provide to the subsequent purchaser--

``(AA) a transaction statement, which shall state that such wholesale distributor, or a member of the affiliate of such wholesale distributor, purchased the product directly from the manufacturer, exclusive distributor of the manufacturer, or repackager that purchased the product directly from the manufacturer; and

``(BB) subject to subclause (II), the transaction history and transaction information.

The full act can be read here on the FDA's website:

<https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act>

Fines for failure to comply with the DSCSA can range from \$1000 per incident to \$500, 000 per entity and should be reported to the FDA as seen here:

<https://www.pharmasalmanac.com/articles/implications-of-serialization-for-the-u.s.-pharma-industry#:~:text=%E2%80%9CFailure%20to%20comply%20with%20DSCSA,penalties%2C%E2%80%9D%20according%20to%20FDA.&text=The%20Federal%20Criminal%20Code%20also,individuals%20and%20%24500%2C000%20for%20entities.>

GOVERNMENT
EXHIBIT

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Real Consequences

The DSCSA was signed by the president and was an act of Congress, meaning that noncompliance will be penalized through legal action. More specifically, the DSCSA (Section 585 (b)(4)(C)) modifies Federal Law 21 U.S.C. 331 to include noncompliance with aspects of the DSCSA as a "Prohibited Act." In addition to compliance dates and requirements for T3 documentation (Transaction History, Transaction Information and Transaction Statement) and serialization, prohibited acts will include reselling or misbranding a product and failing to report issues with shipments and/or suspect or illegitimate product (within 48 hours).

"Failure to comply with DSCSA can lead to fines, suspension or revocation of license, and even potential imprisonment or civil penalties," according to FDA.³ While the DSCSA does not specify what the penalties will be, Federal Law 21 U.S.C. 333 specifies penalties for a prohibited act to include:

- Imprisonment for not more than one year and/or a fine of not more than \$1,000.
- Imprisonment of not more than three years and/or a fine of not more than \$10,000 for subsequent or intentional violations.
- Equitable remedies, such as restitution, disgorgement of profits and product seizure.
- The Federal Criminal Code also authorizes a general fine of up to \$250,000 for individuals and \$500,000 for entities.

The DSCSA also establishes the primacy of the FDA in regulating the pharmaceutical supply chain; the state will not control what penalties are faced under the DSCSA.

It is imperative that Boulevard provide the T3 information for us, as we do not want to be put at risk should we fail to provide accurate information to our customers.

Let me know if you have additional questions or need additional resources.

Thanks,

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